510(k) Summary

DEC 2 4 2013

Manufacturer Name:	Excelsior Medical Corporation
Address:	1933 Heck Avenue Neptune, NJ 07753
Contact Name:	John Linfante
Title:	VP Regulatory and Quality Assurance
Phone Number:	732-643-6088
Fax Number:	732-776-7600
Date Prepared:	November 1, 2013

Device Proprietary Name:	SwabCap®
Device Common or Usual Name:	Device Disinfectant Cap
Classification Name:	Pad, Alcohol, Device Disinfectant
Classification Code:	LKB
Regulation Number:	N/A
Device Classification	Unclassified

Predicate Devices:

Substantial equivalence is claimed to the following device as related to intended use, design, and material characteristics:

- SwabCap®, Excelsior Medical Corporation, K083508

Description of the Device

SwabCap® is a plastic threaded cap that houses a small sponge saturated with 70% isopropyl alcohol. The device is designed to securely fit on swab-able luer access valves to disinfect the valve surface and maintain antiseptic conditions between line accesses. SwabCap® is a sterile, single-use device, provided as a stand-alone product.

Intended Use/Indications for Use

SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

The purpose of this 510(k) is to extend the indications for use to include surface disinfection for up to 7 days.

Summary of Technological Characteristics

The subject SwabCap® has similar technological characteristics as the predicate device in terms of design, chemical composition, and materials of construction.

Both devices are designed with a standard luer thread to fit on swab-able luer access valves. There have been no changes to the product dimensions, antimicrobial agent, and sterilization processes.

Slight modifications of the cap and colorant resin materials, as well as the foil lid cover were made to improve manufacturing efficiency or due to product availability. All changes were made within the same generic material families and were implemented under design controls.

Comparison of Substantial Equivalence

The Substantial Equivalence table below compares the intended use and key technological and design characteristics of the subject and predicate devices. A discussion of the similarities and differences in technological characteristics is provided above.

510(k) Number	**SwabCap® K130975**	**SwabCap® K083508**
Intended Use	SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.	The SwabCap® is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. SwabCap® will disinfect the valve five (5) minutes after application and act as a physical barrier to contamination for up to ninety-six (96) hours under normal conditions if not removed.
Design	Same	Designed with standard luer thread to fit on swab-able luer access valves.
Materials	• Holder – same	• Holder – Alathon M6580

510(k) Number	SwabCap® K130975	SwabCap® K083508
	• Cap – same • Sponge – same • Colorant – Pantone 151C	• Cap – Medical grade Santoprene • Sponge – SUGI absorbent material • Colorant – Pantone 151C
Antimicrobial Agent	Same	70% Isopropyl Alcohol
Dimensions	Same	Diameter 20 mm Height 13.5 mm
Sterility	Same	Gamma irradiated

Non-Clinical Testing

Non-clinical testing including biocompatibility studies, sterilization validation, and antimicrobial testing were undertaken to support the changes to the product and its intended use.

Conclusion

The data provided within the 510(k) submission support that the product is as safe and as effective as the predicate device, and therefore, is substantially equivalent to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

Excelsior Medical Corporation
Mr. John Linfante
Vice President – Regulatory Affairs / Quality Assurance
1933 Heck Avenue
Neptune, NJ 07753

Re: K130975
Trade/Device Name: Swabcap® and Swabflush®
Regulation Number: 21 CFR 880.5200 (SwabFlush); N/A (SwabCab)
Regulation Name: Pad, Alcohol, Device Disinfectant
Regulatory Class: Class II (SwabFlush); Unclassified (SwabCab)
Product Code: NGT (SwabFlush); LKB (SwabCap)
Dated: November 25, 2013
Received: November 26, 2013

Dear Mr. Linfante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130975

Device Name: SwabFlush® (3 mL saline in 10 mL syringe, 5 mL saline in 10 mL syringe, and 10 mL saline in 10 mL syringe)

Indication for Use: The flush syringe is intended for the flushing of IV catheters and IV tubing.

SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S

Division Sign-Off
Office of Device Evaluation

510(k) K130975

Indications for Use

510(k) Number: K130975

Device Name: SwabCap®

Indication for Use: SwabCap® is intended for use on swab-able luer access valves as a cover to protect the luer access valves from potential contamination. The SwabCap® acts as a physical barrier to contamination between line accesses and also serves as a disinfecting cleaner for use prior to line access. SwabCap® will disinfect the valve five (5) minutes after application and maintains a disinfected valve surface for up to seven (7) days if not removed.

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